REMARKS

Claims 1-9, 11, 23-29, and 31-53 are pending in the application. Claim 30 has been cancelled. Claims 1, 4, 5, 23, 34, and 38 have been amended. New claims 42-53 have been added. The specification has been amended to update the priority information on the first page of the application, identify corresponding amino acid residue numbers for disclosed peptide sequences, and update the address for ATCC. Support for the amendments and new claims can be found in Figs. 1A, 1B, and 6A and in the specification at, e.g., paragraphs 0005 to 0007, 0021, 0035, 0037, and 0039 to 0041. These amendments add no new matter.

Specification/Informalities

At page 2 of the Office Action, the Examiner requested corrections to several paragraphs in the specification. Applicants have amended each of the paragraphs identified in the Office Action.

35 U.S.C. §102(b) (Anticipation)

At pages 2-3 of the Office Action, the Examiner rejected claims 1, 4-7, 23, 26, 29, 30, 33, 34, 37, 38, and 41 as allegedly anticipated by Feigelstock et al. (1998) J. Virol. 72:6621-28 ("Feigelstock") as evidenced by Thompson et al. (1998) J. Virol. 72:3751-61 ("Thompson").

Amended claim 1 is directed to an isolated monoclonal antibody or antigen-binding fragment thereof that binds to the extracellular domain of the human KIM-1 polypeptide of SEQ ID NO:7 at an epitope within or overlapping the amino acid sequence of SEQ ID NO:1. Feigelstock describes polyclonal antisera ("anti-GST2" antisera) that binds to havcr-1 proteins on a Western blot (see Feigelstock at page 6625). Feigelstock does not describe a monoclonal antibody that binds to the human havcr-1 protein. As discussed with Examiners Kim and Nolan, for at least this reason, Feigelstock does not anticipate independent claim 1 or the claims that depend therefrom.

Amended claim 23 is directed to an isolated antibody or antigen-binding fragment thereof that binds to the extracellular domain of the human KIM-1 polypeptide of SEQ ID NO:7 at an

epitope within the amino acid sequence SEQ ID NO:1. The anti-GST2 polyclonal antisera described by Feigelstock was raised against a 228 amino acid segment of the simian havcr-1 protein (see Feigelstock at page 6622 and Thompson at pages 3752-53). Nothing in Feigelstock suggests that the polyclonal antisera described therein binds to the polypeptide of SEQ ID NO:7 at an epitope within the 18 amino acid sequence of SEQ ID NO:1. As discussed with Examiners Kim and Nolan, for at least this reason, Feigelstock does not anticipate independent claim 23 or the claims that depend therefrom.

New claim 42 is directed to an isolated antibody or antigen-binding-fragment thereof that binds to the extracellular domain of the human KIM-1 polypeptide of SEQ ID NO:7, when expressed on the surface of a cell, at an epitope within or overlapping the amino acid sequence SEQ ID NO:1. The polyclonal antisera described by Feigelstock does not bind to human havcr-1 on the surface of a cell (see Feigelstock at pages 6625-26). As discussed with Examiners Kim and Nolan, for at least this reason, Feigelstock does not anticipate independent claim 42 or the claims that depend therefrom.

CONCLUSIONS

Applicants submit that all grounds for rejection have been overcome, and that all claims are in condition for allowance, which action is requested.

If Examiners Kim and Nolan identify any remaining issues that may prevent an allowance of the application, please contact the undersigned by telephone prior to issuing a new Office Action.

Enclosed is a check for excess claims fees. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 13751-032001.

Respectfully submitted,

Date: October 5, 2005

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